

5001 Campus Drive
College Park, MD 20740-3835
M-I-18-21

November 27, 2018

TO: Director, Office of State Cooperative Programs
Attn: All Staff, Division of Milk Safety

FROM: Milk and Milk Products Branch (HFS-316)

SUBJECT: Charm Sciences, Inc. CHARM® TRIO Test, Sulfonamides Only

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) has evaluated data supporting the use of the Charm Sciences, Inc. CHARM® TRIO Test for the detection of sulfonamides in raw, commingled cow milk. The CHARM® TRIO Test detects three (3) classes of drugs, Beta lactams, tetracyclines, and sulfonamides. The scope of this evaluation is limited to the sulfonamides. The FDA has previously approved the CHARM® TRIO Test for the detection of Beta-lactams (M-I-18-4)

The FDA evaluation of the data, presented by Charm Sciences, Inc., indicates that the performance of the CHARM® TRIO Test meets the standards established to determine the acceptance of a Test for use in raw, commingled cow milk. The acceptance of the Test for raw, commingled cow milk represents a claim for Sulfadimethoxine and Sulfamethazine. The data has been evaluated in accordance with the standards established for the acceptance of screening tests for monitoring raw, commingled milk in accordance with the provisions of Appendix N-Drug Residue Testing and Farm Surveillance of the Grade "A" Pasteurized Milk Ordinance (PMO).

The NCIMS Executive Board voted to accept the use of this Test for Sulfonamides when used as labeled on April 11, 2018. Attached is the memorandum of acceptance from FDA's CVM.

An electronic version of this memorandum is available for distribution to FDA Milk Specialists, Milk Regulatory/Rating Agencies, Laboratory Evaluation Officers and Milk Sanitation Rating Officers. The electronic version should be widely distributed to State Veterinarians, State Veterinary and Pharmacy Boards, Veterinarian Professional Organizations, representatives of the dairy industry and other interested parties and will be available on the FDA Web Site at <http://www.fda.gov> at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to monica.metz@fda.hhs.gov.



Monica Metz, Chief
Milk and Milk Products Branch

Attachment: FDA CVM Memorandum of Acceptance of the Charm Sciences, Inc.
CHARM® TRIO Test, Sulfonamides Only



Memorandum

**To: Monica Metz, Chief
Milk and Milk Products Branch**

From: Philip James Kijak, Ph.D.

Date: November 26, 2018

Subject: Charm® TRIO Test, Sulfonamides Only

Charm Sciences, Inc. has provided data to FDA supporting the use of the Charm® TRIO test for the detection of Sulfamethazine and Sulfadimethoxine in raw, commingled cow milk. This data has been evaluated in accordance with the standards established for the acceptance of screening tests for raw, commingled cow milk to monitor milk in accordance to the provisions of Appendix N of the Pasteurized Milk Ordinance (PMO).

The Charm® TRIO test detects three classes of drugs, Beta lactams, Tetracyclines, and Sulfonamides. Charm Sciences, Inc. is seeking approval for use of the Charm® TRIO test for PMO testing of milk. This memorandum addresses the review and acceptance of the data provided by Charm Sciences, Inc. for PMO testing of sulfonamide drugs only. The test for has already been approved for the testing of Beta-lactams (M-I-18-4). Tetracyclines will be addressed separately. Charm Sciences, Inc. submitted data for both sulfonamide drugs (Sulfamethazine and Sulfadimethoxine) that FDA requires a test to detect for acceptances.

The 90/95 percent detection levels (ppb) and drug concentration responses are listed below:

DRUG	90/95	Tolerance/Target Testing Level (ppb)
Sulfamethazine	9.2	10
Sulfadimethoxine	7.6	10

The Drug Concentration Response: (Displayed as percent positive based on 30 samples at each concentration.)

**CHARM® SULF TEST: Sulfonamides
DRUG CONCENTRATION RESPONSE**

DRUG	Sulfamethazine	Sulfadimethoxine
Tolerance/Target Level (ppb)	10	10
Drug Concentration (ppb)		
1	13	
2	37	3
4	80	17
6	93	70
8	100	90
10	97	100

RECOMMENDATION

Our evaluation of the data presented by Charm Sciences, Inc. indicates that the performance of this test meets the standards established for acceptance of screening tests for monitoring raw, commingled cow milk for sulfonamides. We recommend that the appropriate announcement be issued to the Regulatory/Rating Agencies and the milk industry advising of the Agency's concurrence with the use of this test as labeled. A revision of M-a-85 and M-I-96-10 should be issued to reflect the acceptance of this test.



Philip James Kijak, Ph.D.
Director, Division of Residue Chemistry
CVM Office of Research